

**U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT
ENFORCEMENT AND REMOVAL OPERATIONS
ICE HEALTH SERVICE CORPS**

LABORATORY SERVICES

**IHSC Directive: 10-01
ERO Directive Number: 11819.3
Federal Enterprise Architecture Number: 306-112-002b
Effective: 11 Mar 2016**

**By Order of the Acting Assistant Director
Stewart D. Smith, DHSc/s/**

- 1. PURPOSE:** The purpose of this issuance is to set forth the policies and procedures for appropriate laboratory services provided by U.S. Immigration and Customs Enforcement (ICE) Health Service Corps (IHSC) clinics in support of the health care screening, diagnosis, treatment, and management of detained aliens.
- 2. APPLICABILITY:** This directive applies to all IHSC personnel, including but not limited to, Public Health Service (PHS) officers, civil service employees and contract personnel. It is applicable to IHSC personnel supporting health care operations in ICE-owned and contracted detention facilities, and to IHSC Headquarters (HQ) staff. Federal contractors are responsible for the management and discipline of its employees supporting IHSC.
- 3. AUTHORITIES AND REFERENCES:**
 - 3-1.** Title 8, Code of Federal Regulations, Section 235.3 ([8 CFR § 235.3](#)), Inadmissible Aliens and Expedited Removal.
 - 3-2** Section 232 of the Immigration and Nationality Act, as amended, Title 8, U.S. Code, Section 1222 ([8 U.S.C. § 1222](#)), Detention of Aliens for Physical and Mental Examination.
 - 3-3.** Title 8, Code of Federal Regulations, Part 232 ([8 CFR 232](#)), Detention of Aliens for Physical and Mental Examination.
 - 3-4.** Section 322 of the Public Health Service Act, as amended, Title 42 U.S. Code, Section 249(a) ([42 U.S.C. § 249\(a\)](#)), Medical Care and Treatment of Quarantined and Detained Persons.

- 3-5.** Title 42, U.S. Code, Section 252 ([42 U.S.C. § 252](#)), Medical Examination of Aliens.
- 4. POLICY:** IHSC provides timely laboratory services to detainees/residents (hereafter referred to as “detainees”) with a documented need for acute or chronic health services.
- 4-1. Staffing and organization.** The licensed vocational nurse (LVN), licensed practical nurse (LPN), registered nurse (RN) or medical technologist (MT) assigned to the laboratory collects and prepares specimens for outside lab work and performs on-site Clinical Laboratory Improvement Amendments (CLIA) waived lab tests under the supervision of the health services administrator (HSA) and guidance of the Clinical Director (CD). Each laboratory obtains a CLIA waiver certificate for on-site testing.
- 4-2. Guidelines for processing lab services.**
- a. **Ordering.** Only physicians, dentists, physician assistants and nurse practitioners can order laboratory tests. The physician or designee should document all laboratory orders in the detainee’s health record and schedule a lab review appointment by a provider, as appropriate. Completed lab collections, to include date collected, date received, date reviewed and test(s) performed can be accessed in the 1101 Historical Lab Orders Enterprise Business Optimizer (EBO) Report. Each order is sent via the interface between LabCorp and eClinicalWorks (eCW) with a test code, test name, requisition control number and National Provider Identifier (NPI) number.
 - b. **Lab Results Reporting.** Within the lab window in the electronic health record (eHR), all laboratory results are assigned to the ordering provider or designee for evaluation. The provider or delegate/surrogate provider should review normal and abnormal labs, via the Lab Jellybean in eCW, within 24 hours. If the laboratory results are received on a weekend or holiday, the provider or delegate/surrogate provider should review the results by the next business day. In addition, the provider who reviews the lab result should ensure a follow-up appointment is scheduled with the detainee to discuss the lab results. If the clinic coordinator or designated nursing staff member receives any lab values that fall significantly outside the normal range and/or may represent life-threatening values (i.e., critical lab values) after-hours, the on-call provider should be contacted for further instructions or orders. These instructions or orders should be documented in the detainee’s eHR via a Telephone Encounter.

- c. **Consent Issues.** The general consent obtained at the intake process includes consent for all laboratories ordered as indicated, including human immunodeficiency virus (HIV) testing.

4-3. On-site lab services. Minimum on-site laboratory services include: glucose finger stick, urinalysis dipstick, urine pregnancy test (for sites with female detainees), rapid strep test, influenza test and fecal occult blood test. There is a procedure manual for each service, including protocols for the calibrations of testing devices to assure accuracy.

- a. **CLIA waived tests.** CLIA requires that all laboratories that examine materials from the human body for diagnosis, prevention, or treatment purposes are certified by the Secretary of Health and Human Services. (The HSA, or designee, maintains documentation on-site that diagnostic services are certified or licensed to provide that service.) The Centers for Medicare and Medicaid Services (CMS) operates the CLIA laboratory certification program for the Secretary of Health and Human Services in conjunction with the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). Pursuant to CLIA law ([Title 42, Code of Federal Regulations, Part 493](#)), waived laboratories can only perform tests that the CDC and FDA determine as so simple that there is little risk of error. IHSC medical facilities may perform certain waived tests on-site. Each facility must maintain current CLIA certification. All staff members that perform CLIA tests are required to pass an Ishihara Color Test for color blindness in order to interpret color dependent lab tests.

Procedures. Each CLIA waived test is performed in accordance with the manufacturer's instructions and local operating procedures. Each test must have quality control testing performed as instructed by the manufacturer and the value range of the specific test must be documented in a local CLIA lab log. CLIA lab results for detainees are electronically recorded in the detainee's record via the lab window in eCW.

4-4. Off-site lab services. Any outside laboratory facility used must be accredited by the College of American Pathologists (CAP) or licensed by the CDC. Local operational procedures for these services include the following: 1) name, address and telephone number of the clinical laboratory contracted by the agency; 2) how routine and stat results are obtained; 3) bill review process; and 4) inventory and ordering process for laboratory supplies.

- a. **Preparing specimen for transport.** All specimens are packaged for transport, with a record of all specimens sent to the reference

lab, in accordance with the following: 1) collection tubes are prepared according to the Directory of Services Manual provided by the contractor; and 2) specimens are labeled with the detainee's name, requisition number, date of birth, and date and time of collection as generated by the eHR.

- b. **Specimen collection.** For specific instructions on the collection of specimens, refer to the manual of the local laboratory service provider.
- c. All off-site laboratory results should be brought to the attention of the medical provider for further evaluation, as warranted. If paper lab results are received, the medical provider should sign, review and date the original report and forward the report to Medical Records for inclusion in the detainee's health record. After the provider reviews the paper lab results, the report should be scanned into the detainee's eHR. If received electronically via the eCW/LabCorp Interface, the provider or delegate/surrogate provider should review the lab results, via the Lab Jellybean in eCW, within 24 hours, or if the results are received on a weekend or holiday, by the next business day. The provider who reviews the lab results should also ensure a follow-up appointment is scheduled with the detainee to discuss the lab results.

5. **PROCEDURES:** No additional procedures.

6. **HISTORICAL NOTES:** This document replaces IHSC Directive 10-01: Laboratory Services, effective 15 November 2015. Changes made to 4-3.

7. **DEFINITIONS:** See definitions for this policy in the IHSC Glossary located on SharePoint.

8. **APPLICABLE STANDARDS:**

8-1. Performance-Based National Detention Standards (PBNDS):

PBNDS 2011:

4.3: Medical Care.

8-2. ICE Family Residential Standards:

4.3: Medical Care.

8-3. American Correctional Association (ACA):

Performance-Based Standards for Adult Local Detention Facilities, 4th edition:

4-ALDF-4C-19: Chronic Care.

8-4. National Commission on Correctional Health Care (NCCHC):

Standards for Health Services in Jails, 2014:

J-D-04: Diagnostic Services.

J-G-01: Chronic Disease Services.

- 9. PRIVACY AND RECORDKEEPING.** IHSC maintains detainee health records in accordance with the Privacy Act and as provided in the Department of Homeland Security (DHS)/ICE-013 Alien Health Records System of Records Notice, 80 Federal Register 239 (January 5, 2015). The records in the eHR/ eCW are destroyed ten (10) years from the date the detainee leaves ICE custody. Retention periods for records of minors may differ. Paper records are scanned into the eHR and are destroyed after upload is complete.

Protection of Health Records and Sensitive Personally Identifiable Information (PII).

- 9-1.** Staff must keep all health records, whether electronic or paper, secure with access limited only to those with a need to know. Staff should lock paper records in a secure cabinet or room when not in use or not otherwise under the control of a person with a need to know.
- 9-2.** Only authorized individuals with a need to know are permitted to access health records and sensitive PII.
- 9-3.** Staff should reference the Department of Homeland Security *Handbook for Safeguarding Sensitive Personally Identifiable Information* (March 2012) at:

(b)(7)(E)

1 when additional information concerning safeguarding sensitive PII is needed.

- 10. NO PRIVATE RIGHT STATEMENT.** This directive is an internal policy statement of IHSC. It is not intended to, and does not create any rights, privileges, or benefits, substantive or procedural, enforceable against the United States; its departments, agencies, or other entities; its officers or employees; or any other person.